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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/721,550	11/22/00	REICH N	510015-234

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OPPENHEIMER WOLFF & DONNELLY LLP
2029 CENTURY PARK EAST
38TH FLOOR
LOS ANGELES CA 90067-3024

EXAMINER	
TAYLOR, J	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 03/19/02

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/721,550	REICH, NORBERT	
	Examiner	Art Unit	
	Janell Taylor Cleveland	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 22 November 2000 .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-19 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 14 and 15 recite the limitation "the bead of claim 6 [or 7]." There is insufficient antecedent basis for this limitation in the claim because claims 6 and 7 do not recite a bead. It is believed that the claims should have depended from claim 13. Appropriate correction is required.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) The invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 1, 2, 4, 5, 8, 9, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by McGall et al.

Claim 1 is drawn to a substrate having a surface area, the surface area comprising attached labeled probe molecules. Claim 2 is drawn to the label being fluorescent. Claim 4 is drawn to the labeled molecules being nucleotides. Claim 5 is drawn to those nucleotides being nucleotide analogs. Claim 8 is drawn to the molecules being carbohydrates. Claim 9 is drawn to the substrate being a microarray. Claim 14 is drawn to the substrate being a bead.

McGall et al. teaches "Oligonucleotide analogue arrays attached to solid substrates...target nucleic acids which comprise nucleotide analogs are bound to oligonucleotide analogue arrays." (Abstract). McGall also teaches that the "oligonucleotide probe arrays also comprise nucleotide analogues" (Col. 2, lines 50-51). McGall also teaches that the substrate may be a bead. (Col. 14, line 46). McGall also teaches detection by labeling probe molecules. (Col. 12 line 40). Lastly, nucleic acids are carbohydrates, so McGall fully anticipates this claim. Therefore all of the limitations of claims 1, 2, 4, 5, 8, 9, and 13 are anticipated by McGall et al.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 3, 10-12, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGall et al.

Claim 3 is drawn to the fluorescent wavelength being between 300-700 nm. Claims 10-12 are drawn to the microarray being divided into quadrants wherein each different quadrant has labeled probe molecules of different sequences, and the amount of quadrants and probes on the microarray. Claim 16 is drawn to a method comprising detecting a difference in the probes before and after hybridization.

As disclosed above, McGall et al. teaches "Oligonucleotide analogue arrays attached to solid substrates...target nucleic acids that comprise nucleotide analogs are

bound to oligonucleotide analogue arrays." (Abstract). McGall also teaches that the "oligonucleotide probe arrays also comprise nucleotide analogues" (Col. 2, lines 50-51). McGall also teaches that the substrate may be a bead. (Col. 14 line 46). McGall also teaches detection by labeling probe molecules. (Col. 12 line 40).

McGall et al. does not specifically teach quadrants on the microarray, or the amount of probes on the microarray. McGall also does not teach the fluorescent wavelength. McGall also does not teach measuring fluorescent levels before and after hybridization.

It would have been obvious to one of ordinary skill in the art at the time of the invention that the fluorescent range would have been commensurate with the fluorescent probe that was used. At the time of the invention, a wide variety of probes at a wide variety of wavelengths were known, including those falling in the range of 300-700 nm. Therefore, it would have been obvious that the probe being used may have been detectable in this range.

It would have also been obvious to one of ordinary skill in the art to separate the areas of the microarrays into different quadrants having different probes. This was, in fact, well known in the art at the time of the invention. McGall et al. teaches "Provided that the spatial location of each probe in an array is known, the data from the probes is collected and processed to yield the sequence of a target irrespective of the physical arrangement of the probes on a chip." (Col. 15 lines 55-59). It would have therefore been obvious to place the microarray into quadrants because the target was detectable as long as the area of the microarray was known. Furthermore, the amount of

quadrants and probes on the array was well known and it would have been obvious that the range given would have worked with the array of McGall.

Lastly, it would have been obvious to one of ordinary skill in the art to measure the level of fluorescence of a sample before and after hybridization. This would have been obvious because it was well known that this would have enabled one of ordinary skill to detect changes in the level of fluorescence due to hybridization.

5. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGall et al as applied to claims above, and further in view of Gelfland et al. (USPN 5,804,375).

The claim is drawn to the nucleotide analog being 2-amino purine.

The teachings of McGall et al. were discussed above.

McGall et al. does not teach 2-amino purine as the nucleotide analog.

Gelfland et al. teaches "...2-amino purine...is another analog that could be used in probe synthesis. The probes containing such nucleotide derivatives may be hydrolyzed to release much more strongly fluorescent mononucleotides..." (Col. 12, line 35).

It would have been obvious to one of ordinary skill in the art at the time of the invention that the nucleotide analog of McGall may have been 2-amino purine. This is because it was a well known nucleotide analog at the time of the invention, and was useful in that it produced a strong fluorescent signal when hydrolyzed. For this reason it would have been obvious to one of ordinary skill in the art to use it with the invention of McGall.

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGall as applied to claims above, and further in view of Scholin et al. (USPN 6,187,530 B1).

Claim 7 is drawn to the probe molecule being comprised of amino acids.

The teachings of McGall et al. are disclosed above.

McGall et al. does not teach an amino acid probe.

Scholin et al. teach antibody probes (Col. 9, line 59), which, of course, are comprised of amino acids, on an array.

It would have been obvious to one of ordinary skill in the art at the time of the invention that the probe of claim 1 may have been comprised of amino acids. This is because amino acid probes were well known in the art at the time of the invention and it was well known that they were capable of being used with an array, as in the one disclosed by Scholin et al.

7. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGall as applied to claims above, and further in view of Mandecki (USPN 6,001,571).

The claims are drawn to the bead being formed of ferromagnetic metal with a polymeric coating, and the amount of probes on the bead.

The teachings of McGall et al. are disclosed above.

McGall does not teach that the bead is ferromagnetic, or the amount of probes contained thereon.

Mandecki teaches "In solid phase assays, small beads...are used to capture the analyte. Solid-phase microparticles may be made of different materials, such as

glass...Some beads are made of ferromagnetic materials to facilitate their separation from complex suspensions of mixtures." (Col. 1 lines 20-26).

It would have been obvious to one of ordinary skill in the art at the time of the invention that the bead of McGall et al. may have been made up of ferromagnetic material, in order to facilitate its separation from complex suspension of mixtures. It would also have been obvious that a wide range in the number of probes attached to the beads may have been used, as this was well known in the art at the time of the invention.

Summary

Claims 14 and 15 are rejected under 35 U.S.C. 112, second paragraph. Claims 1, 2, 4, 5, 8, 9, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by McGall et al. Claims 3, 10-12, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGall et al. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGall et al as applied to claims above, and further in view of Gelfland et al. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGall as applied to claims above, and further in view of Scholin et al. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGall as applied to claims above, and further in view of Mandecki.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor Cleveland, whose telephone number is (703) 305-0273.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (703) 308-1152.

Any inquiries of a general nature relating to this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1634 via the PTO Fax Center using (703) 305-3014 or 305-4227. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989.)

Janell Taylor Cleveland

March 14, 2001

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

3/16/01